DOCKET NO.: CEPH-1066 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Scott, Reaume and Dorfman

Serial No.: **09/621,897** Group Art Unit: **1633**

Filed: **July 20, 2000** Examiner: **D. Nguyen**

For: **Gene Targeted Non-Human Mammal With Human Fad Presenilin Mutation And Generational Offspring**

EXPRESS MAIL INFORMATION

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DATE OF DEPOSIT: October 24, 2001

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

RESPONSE TO RESTRICTION REQUIREMENT

The present Response is in regard to the Restriction Requirement mailed September 24, 2001 in connection with the above-identified patent application.

As a preliminary matter, Applicants acknowledge receipt of the "Attachment for PTO-948" outlining changes for prosecution of applications containing drawings. To date, however, no Form PTO-948 has been received. Accordingly, the "Attachment for PTO-948" is not relevant in the present application.

The Examiner has restricted claims 1-76 into eighteen (18) groups. Group I contains claims 1-26 drawn to gene-targeted, non-human mammals heterozygous for human presenilin-1 mutation, human FAD Swedish mutation, and humanized Aβ gene, offspring thereof, and screening and identifying methods related thereto. Group II contains claims 27 and 35 drawn to methods of employing compounds identified by claim 19. Group III contains claims 28 and 36 drawn to methods of employing compounds identified by claim 20. Group IV contains claims 29 and 37 drawn to methods of employing compounds identified by claim 21. Group V contains claims 30 and 38 drawn

to methods of employing compounds identified by claim 22. Group VI contains claim 31 drawn to a compound identified by the method of claim 11. Group VII contains claim 32 drawn to a compound identified by the method of claim 12. Group VIII contains claim 33 drawn to a compound identified by the method of claim 13. Group IX contains claim 34 drawn to a compound identified by the method of claim 14. Group X contains claims 39-64 drawn to gene-targeted, non-human mammals heterozygous for human presenilin-1 mutation and human FAD Swedish APP695 mutation, offspring thereof, and screening and identifying methods related thereto. Group XI contains claims 65 and 73 drawn to methods of employing compounds identified by claim 57. Group XII contains claims 66 and 74 drawn to methods of employing compounds identified by claim 58. Group XIII contains claims 67 and 75 drawn to methods of employing compounds identified by claim 59. Group XIV contains claims 68 and 76 drawn to methods of employing compounds identified by claim 60. Group XV contains claim 69 drawn to a compound identified by the method of claim 49. Group XVI contains claim 70 drawn to a compound identified by the method of claim 50. Group XVII contains claim 71 drawn to a compound identified by the method of claim 51. Group XVIII contains claim 72 drawn to a compound identified by the method of claim 52.

Applicants elect herein group X containing claims 39-64 drawn to gene-targeted, non-human mammals heterozygous for human presenilin-1 mutation and human FAD Swedish APP695 mutation, offspring thereof, and screening and identifying methods related thereto with traverse. Even if the Examiner still considers the groups of claims to be patentably distinct, § 803 of the M.P.E.P. mandates two criteria for a proper requirement for restriction: 1) the inventions must be independent or distinct; ***and*** 2) there must be a serious burden on the examiner. For purposes of initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in M.P.E.P. § 808.02. The Examiner has not met this *prima facie* burden.

Indeed, the Examiner has not shown separate status in the art or a requirement for a different field of search. Each of Groups II-V, for example, have been classified into identical classes (classes 514 and 536) and subclasses (subclasses 44 and 23.1), indicating a lack of serious burden.

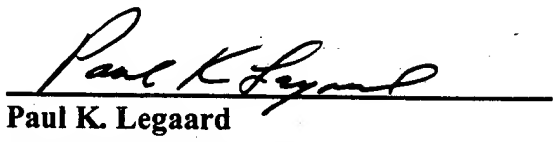
Thus, Groups II-V ***must*** be combined into a single group. Groups VI-IX (claims 31-34), for example are directed to compounds identified by claims 11-14, respectively. Applicants fail to understand how claims 31-34 can be classified into three different classes when they are all directed to compounds identified by the same methods steps of claims 11-14, respectively. Indeed, the only difference between claims 11-14 is the mammal employed (claim 11 employs the mammal of claim 1; claim 12 employs the mammal of claim 2; claim 13 employs the mammal of claim 9; claim 14 employs the mammal of claim 10). The only difference between claims 1 and 2 is that claim 1 recites "heterozygous" and claim 2 recites "homozygous." Further, claims 9 and 10 are directed to the generational offspring of the mammals of claims 1 and 2, respectively. Thus, Groups VI-IX (claims 31-34) should quite clearly be combined into a single group. Likewise, Groups XI-XIV should be combined into a single group and Groups XV-XVIII should be combined into a single group.

Accordingly, Applicants respectfully request that the restriction of the claims be reconsidered and, at a minimum, claims 27-30 and 35-38 be combined into a single group, claims 31-34 be combined into a single group, claims 65-68 and 73-76 be combined into a single group, and claims 69-72 be combined into a single group.

The Office Action also requires Applicants to elect species falling within four categories. Although Applicants submit that the species election outlined by the Examiner is misplaced, Applicants elect, with traverse, the following species from the four categories recited by the Examiner: category 1 (species of PS-1 mutation) -- Applicants elect P264L; category 2 (species of human FAD Swedish mutation) -- Applicants elect APP695; category 3 (species of mammal) -- Applicants elect rodent; and category 4 (species of tissue sample) -- Applicants elect brain tissue. In regard to the species election for human FAD Swedish mutation, Applicants point out that there is only one "Swedish mutation." Indeed, APP695 is a truncated protein having 695 amino acids produced by mutations in which positions 670-671 have been altered from KM to NL. Claims 39-64 are readable on the elected species.

Applicants submit that the present response is complete and complies with the requirements of 35 U.S.C. § 121.

Respectfully submitted,



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Date: **October 24, 2001**

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